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February 1, 2021
VIA ECF

The Honorable Karen M. Williams
United States Magistrate Judge
United States District Court - District of New Jersey
Mitchell H. Cohen U.S. Courthouse
4th & Cooper Streets, Room 2060
Camden, NJ 08101

The Honorable Thomas I. Vanaskie (Ret.)
Special Master for Discovery
Stevens & Lee
1818 Market Street, 29th Floor
Philadelphia, PA 19103

Re: In re Valsartan/Irbesartan/Losartan MDL

Dear Judge Williams and Judge Vanaskie:

I. INTRODUCTION

Defendants' January 20, 2021 letter brief is predicated on the nonsensical argument that Defendants lack the possession, custody or control over documents kept by their contractual manufacturing partners simply because Plaintiffs have been unable to point to the exact language kept in contracts *Defendants themselves have refused to produce to Plaintiffs*. Defendants cannot be permitted to skirt by on these bald assertions without more. The practical reality of drug manufacturing dictates that Manufacturers, such as Defendants, must be able request documents from their former, current, or prospective contractual partners used for the manufacture regulated drug products sold in the United States. Indeed, this reality is confirmed by the fact that some Defendants in this case have done so. [1] Quashing the subpoenas at issue here would only serve to put Plaintiffs at a severe tactical disadvantage. The Court should compel (1) the production of all contracts with these third-party subpoena entities kept in the possession of the Defendants arguing for the motion to quash, (2) production of whatever documents can be requested and produced by these subpoena entities, or (3) sworn affidavits from the persons most knowledgeable about the efforts the Defendants made to obtain these documents from the entities.

II. FACTUAL BACKGROUND

On September 30, 2020, Plaintiffs sent Defense counsel a list of all entities to which they planned on serving third-party subpoenas. Plaintiffs also emailed Defendants on October 2, 2020 and asked Defendants to let them know if they believed any entity on the list did not perform work or did not possess documents relating to issues in this MDL. Plaintiffs

subsequently met and conferred with counsel for Defendants throughout the fall. ECF No. 705-1, ¶ 3-11.

While Plaintiffs' efforts at identifying the universe of third parties involved in this litigation have been hampered by Defendants' delayed production of custodial documents,[2] Plaintiffs nevertheless have continued to meet and confer with Defendants before and since the most recent Court hearings where these issues have been addressed. Plaintiffs have already agreed to narrow at least 20 subpoenas. The present dispute is what remains after these extensive meet and confers.

During the oral argument on Defendants' Omnibus Motion, the Court decided to permit additional briefing on a limited subset of issues:

> By January 20, 2021, defendants are granted leave to serve a supplemental letter brief regarding whether they are in possession, custody, or control of the disputed foreign entities' documents/ESI. Plaintiffs may respond by February 1, 2021. Defendants may reply by February 5, 2021. The Court determines that the present record is not sufficiently developed for it to make an informed decision on this important issue.

ECF No. 727, ¶ 6.

The foreign third parties addressed by Defendants in their January 20, 2021 letter brief are all directly related to the contamination at issue in this case. Azbil Telstar Technologies ("Azbil") performed audits of ZHP's facilities, including the facility that manufactured U.S. grade Valsartan. VXL Life Sciences ("VXL") and Chemo Group India ("Chemo Group") purchased API from ZHP. Linhai Huanan Chemical Co. Ltd. ("Linhai"), Lantech Pharmaceutical Ltd. ("Lantech"), and Snehaa Solvents ("Snehaa") supplied raw materials and solvents to ZHP, Aurobindo, and Mylan, respectively, that was used in Valsartan. Sipra Labs, Ltd. ("Sipra") performed raw material testing for Torrent.

Aurobindo argues that it has already produced all documents in its possession, custody, and control from the foreign third parties connected to it. As it pertains to Aurobindo, Plaintiffs have directed subpoenas to the following foreign third parties: Altus Formulation ("Altus"); AXIS Clinicals, Ltd. ("AXIS"); Cybernetik Technologies P Ltd. ("Cybernetik"); Lantech Pharmaceutical Ltd. ("Lantech"); and Vigilate Biopharma Pvt Ltd. ("Vigilate").

Altus performed quality audits for Aurobindo. AXIS conducted bioequivalence studies on Valsartan for Aurobindo. Cybenetik supplied Aurobindo with drum washing and drying stations. Lantech supplied recovered solvents to Aurobindo, which were used in U.S. grade Valsartan. Vigilate assisted Aurobindo with its recall of Valsartan. Notably, Aurobindo does not raise arguments about the relevance of these entities and instead argues that it does not have the ability to request documents from these companies that it worked closely with when making, contaminating, and recalling Valsartan. Because this argument is distinct from the position taken by the rest of the Defendants, Plaintiffs address this separately below.

III. ARGUMENT

A. The Court Has the Power to Compel Production of These Foreign Third-Party Documents

Defendants argue that these foreign third parties are outside the Court's jurisdiction. ECF No. 766, 1/20/21 Def. Ltr Brief at 4. However, the fact that a court cannot exercise jurisdiction over a non-party does not mean documents in that non-party's possession are shielded from the reach of the court. *Afros S.P.A. v. Krauss-Maffei Corp*., 113 F.R.D. 127, 129 (D. Del. 1986) ("If a party has control over or shares control of documents with a third person, then a court can order production by means of its power over the party litigant.").

Because the Court is vested with this authority, the only remaining issue is "whether a litigant subject to the jurisdiction of the court has sufficient control over documents in the possession of third parties." *Id*. As is demonstrated below, the Parties do have control over the documents in question. Plaintiffs therefore respectfully request the Court order production of the foreign third-party documents over which Defendants have control.

B. Defendants Cannot Be Permitted to Skirt Their Discovery Obligations, Only to Lambast Plaintiffs for Being Unable to Cite Language in Contracts Defendants Themselves Have Not Produced

In their letter to the Court, Defendants never once definitively declared (either through appending a contract or sworn testimony from a corporate witness) that their contractual agreements with the third parties at issue in this motion somehow preclude document demands. This is notable. Instead, the entirety of Defendants argument rests on the fact that Plaintiffs have not met their burden in pointing to the exact language or terms of these contractual relationships. What Defendants fail to note, however, is that Plaintiffs ability to point to such terms has been frustrated by Defendants' repeated refusal to produce contractual documents within their own possession, and response to Plaintiffs' Requests for the Production of Documents ordered by the Court in 2019.

Nevertheless, and anticipating the arguments Defendants make in their Letter Brief, following the last hearing, Plaintiffs separately wrote to counsel for ZHP, Aurobindo, and Torrent and requested copies of these contracts as to any remaining disputed entities. Declaration of Ben Stellpflug, ¶ 3. To date, no defendant has produced additional contracts.[3] Declaration of Ben Stellpflug, ¶ 4-9. Defendants brought this motion and consequently have the burden of proving these subpoenas should be quashed, but they have refused to produce documents that show their lack of access to work product created at their request.

Beyond this, contracts are not the only manner of establishing control over documents. If a party to litigation has the practical ability to obtain discovery from a non-party, courts in the Third Circuit have compelled production. *See Moretti v. Hertz Corporation*, 2018 WL 4693473, at *5 (D. Del. Sept. 30, 2018) (citing *Shcerbakovskiy v. Da Capo Al Fine, Ltd.*, 490 F.3d 130, 138 (2d Cir. 2007) ("[I]f a party has access and the practical ability to possess documents not

available to the party seeking them, production may be required."). Further, Third Circuit courts have construed this definition of control broadly, finding that "[t]he test to determine whether a corporation has custody and control over documents located with [a foreign] affiliate is not whether the corporation has legal title to this documents … Rather, the test focuses on whether the corporation has 'access to the documents' and 'ability to obtain the documents.'" *Dartell v. Tibet Pharmaceuticals, Inc.*, 2016 WL 11653632, at *2 (D.N.J. Fed. 29, 2016). Whether a party has the "practical ability" to obtain documents turns upon (1) the corporate structure encompassing different parties, (2) the nonparty's connection to transaction at issue, and (3) to what degree nonparty will receive benefit of any award in case. *Afros*, 113 F.R.D. at 129.

Here, Defendants undoubtedly have the practical ability to obtain the documents sought by Plaintiffs' foreign third-party subpoenas. This analysis turns further on the fact that each and every one of these foreign third parties are directly connected to the transaction at issue, as contemplated by *Afros*. *Id*. Defendants worked directly with these third parties in ways that connect directly to the claims and defenses at issue in this case. Defendants should not be able to avoid production of this important discovery based on a situation of their own making.

While Plaintiffs are unable to point to the precise contractual language pertaining to these contracts due to Defendants' obfuscation, guidance documents promulgated by the Food and Drug Administration ("FDA") guide Plaintiffs' understanding that these documents can be readily requested. Indeed, in providing guidance on the terms that should be contained within contracts between Drug Manufacturers and suppliers (such as the third parties at issue in this letter), the FDA unequivocally states that, "[t]he quality agreement should define expectations between the contract facility and the owner to review and approve documents." *See* Exhibit A, FDA Guidance on Supplier Agreements, at 10. Moreover, the quality agreement should also define the Defendants' and third parties' roles in "making and maintaining original documents or true copies in accordance with CGMP." *Id*. The contracts must also indicate how the "original documents or true copies" will be made "readily available for inspection." *Id.*

The FDA guidance also contradicts Defendant Mylan's argument that even if, *arguendo*, Mylan once could have obtained documents from vendors pursuant to the supplier quality agreement entered by the Parties, it now cannot because there is no active contractual relationship between the Parties. The FDA makes clear that the document retention timing is not dictated by the dates of the contract. Rather, the FDA states that the quality agreement should also indicate that "electronic records will be stored in accordance with CGMP and will be immediately retrievable during the required *record-keeping time frames established in applicable regulations." Id.* (emphasis added).

C. Hague Service is Not the Exclusive Means of Obtaining Foreign Discovery

Defendants go on to argue that the only option Plaintiffs have is to execute service of these subpoenas via the Hague Convention. ECF No. 766, 1/20/21 Def. Ltr Brief at 4-5. However, international service pursuant to the Hague Convention is not the exclusive means through which foreign discovery can be obtained. *See In re Automotive Refinishing Paint*, 229 F.R.D. 482, 495 (E.D. Pa. 2005) (concluding that the Hague Convention was "intended as a permissive supplement, not a preemptive replacement, for other means of

obtaining evidence located abroad"); *see also In re Diet Drugs (Phentermine, Fenfluramine, Dexfentluramine) Products Liability Litigations*, 1998 WL 1969647, at *9-10 (E.D. Pa. Nov. 13, 1998) (allowing foreign discovery to be taken via the Hague Convention, but only because "the taking of discovery under the Hague Convention would not hinder the time schedule for discovery ordered in this action.").

This fact is especially important in the context of the discovery deadlines the parties had in this case. Requiring Plaintiffs to undergo Hague service would likely prevent Plaintiffs from obtaining any of this important discovery from foreign third parties, due to the protracted nature of this form of service. Indeed, when Plaintiffs were required to serve certain parties at the outset of this case, service took several months. In light of the Court's recent scheduling order, requiring depositions to be completed by March, requiring Plaintiffs to accomplish service on these third parties via the Hague Convention is the functional equivalent to the Court barring Plaintiffs from obtaining these documents entirely.

D. ZHP Has the Practical Ability to Obtain the Requested Documents from Its Corresponding Third Parties

ZHP contends that because Plaintiffs have not pointed to specific language in specific contracts between ZHP and Azbil, VXL, and Chemo Group, that ZHP has no obligation to obtain the requested third-party discovery from any of these three foreign entities. ECF No. 766, 1/20/21 Def. Ltr Brief at 8-11. However, again, this is not the standard. ZHP has the practical ability to obtain the document sought by Plaintiffs' subpoenas directed to these three entities. Azbil is a service provider that has performed audits of ZHP's facilities, including the facility that manufactured Valsartan that was sold in the United States. For example, ZHP provided Azbil with letters of authorization, which authorized Azbil to share these audit reports with outside parties. *See, e.g.,* ECF No. 766-6, Ex. F to 1/20/21 Def. Ltr Brief. Now ZHP argues that it cannot obtain documents from Azbil. This is not true. ZHP has the ability to obtain the documents sought by Plaintiffs' subpoena to Azbil, and they should be compelled to produce them.

VXL and Chemo Group both purchased API from ZHP. It is absurd on its face to argue that ZHP does not have the practical ability to obtain documents from a service provider or customer. Further, these third parties are directly connected to the transaction at issue in this litigation, as the contamination in this case is believed to have originated in the API and raw materials that ultimately went into the Valsartan.

ZHP goes on to argue that it should not have to obtain and produce documents from its own subsidiary, Linhai, and relies upon caselaw that states that parent companies cannot be held liable for acts of its subsidiaries (Linhai is a subsidiary of ZHP). ECF No. 766, 1/20/21 Def. Ltr Brief at 11. However, their argument is a red herring and ignores the fact that ZHP is nonetheless obligated to produce documents over which it has control. Further, the Third Circuit has held that "where the subsidiary was an agent of the parent in the transaction giving rise to the suit," both the party and non-party had control over each other's documents. *Gerling Intern. Ins. Co. v. C.I.R.*, 839 F.2d 131, 140 (3d Cir. 1988). Accordingly, due to both the close working relationship and the principal-agent relationship on the very transaction that gave rise to the

present suit (Linhai supplied raw materials to ZHP, and the contamination issue has been traced back to raw materials and API that were used in Valsartan), ZHP should be compelled to obtain and produce responsive documents from Linhai.

Accordingly, ZHP should be compelled to produce the relevant contracts related to these third parties, obtain and produce responsive documents from these four third parties, or produce a sworn affidavit with a person most knowledgeable declaring why they are unable to do so.

E. Aurobindo Must Identify Documents Obtained from Third Parties Produced in their Production

Aurobindo argues that it has already produced all documents in its "possession" that would be responsive to Plaintiffs' foreign subpoenas. ECF No. 766, 1/20/21 Def. Ltr Brief at 12. This response does not comply with the plain language of the Federal Rules, which require a party to produce not only documents in its possession, but also those within its "custody or control." Fed. R. Civ. P. 26; 34. Control can be defined as the practical ability to obtain documents. *Moretti*, 2018 WL 4693473, at *5; *Dartell*, 2016 WL 11653632, at *2 If Aurobindo has already produced all documents it has the practical ability to obtain, then Plaintiffs simply request that Aurobindo be compelled to formally respond to Plaintiffs' foreign subpoenas, pointing to Bates numbers for documents that are responsive and have been produced. Otherwise, if Aurobindo has really only produced responsive documents that are in its "possession" (as opposed to its control), then Plaintiffs request that Aurobindo be ordered to obtain and produce all documents it has the practical ability to obtain from these foreign third parties.

AXIS conducted bioequivalence studies on Valsartan for Aurobindo. Cybenetik supplied Aurobindo with drum washing and drying stations. Lantech supplied recovered solvents to Aurobindo, which were used in U.S. grade Valsartan. Vigilate assisted Aurobindo with its recall of Valsartan. Aurobindo cannot argue that it does not have the ability to obtain these documents, so it instead argues that Plaintiffs' only option is to prove legal control via specific language in specific contracts with each entity. As articulated above, courts have compelled production when a party has the practical ability to obtain foreign third-party documents, especially when the third party in question is closely connected to the transaction at issue in the litigation. *Afros*, 113 F.R.D. at 129. Plaintiffs should not be excluded from this important third-party discovery simply because Aurobindo refuses to provide the pertinent contracts. Because Aurobindo has the practical ability to obtain these foreign third-party documents, it should be compelled to do so.

F. Mylan Has the Practical Ability to Obtain the Requested Documents from Its Corresponding Third Parties

Mylan argues that the contracts cited by Plaintiffs, which evidence the relationship between Mylan and Lantech and Snehaa, respectively, are not relevant to this inquiry because they have expired. ECF No. 766, 1/20/21 Def. Ltr Brief at 13-14. As discussed *supra*, FDA guidance requires that documents be kept and maintained (at a minimum) according to the document retention periods delineated in the regulations. The obligation to retain documents pursuant to the Food and Drugs Cosmetic Act is completely divorced from the arbitrary dates in

a contract. *See* Ex. A, FDA Guidance on Supplier Agreements. Both Lantech and Snehaa supplied Mylan with solvents that ultimately were used in Valsartan that was sold in the United States pursuant to a drug application on file with the FDA. If the FDA were to ask Mylan for information that was necessarily kept at Lantech or Snehaa, there is no doubt that Mylan would be able to retrieve such documents, and retrieve them quickly. Indeed, this is precisely what Mylan has done throughout the entirety of the recall. Only now in the context of this litigation does Mylan claim it cannot be done. Mylan's discovery obfuscation should not be rewarded, and Mylan should be compelled to obtain and produce documents responsive to Plaintiffs' subpoenas directed to Lantech and Snehaa (or produce a sworn affidavit detailing why it cannot produce such records).

G. Torrent Has the Practical Ability to Obtain the Requested Documents from Sipra Labs, Ltd.

It is absurd on its face to argue that Torrent does not have the practical ability to obtain documents from a company that provided raw material testing for it. Sipra Labs was hired by Torrent to provide regulatory complaint research and development. Torrent would not have engaged a lab to test its products and keep its work product secret. There would be no point in such an arrangement. For Torrent to now pretend that it has no access to work product that was created at its request for the purpose of Torrent using that same data is foolhardy.

Torrent has the practical ability to obtain these documents from Sipra, and this third-party is directly connected to the transaction at issue in this case. Accordingly, Torrent should be ordered to produce the relevant contract with Sipra Las, and obtain and produce documents responsive to Plaintiffs' subpoena from Sipra (or produce a sworn affidavit detailing why it cannot produce such records).

IV. CONCLUSION

Defendants' delay strategy has already placed Plaintiffs in a position requiring them to review mountains of documents when depositions are already are underway, and the deadline to complete them is rapidly approaching. The longer Defendants create procedural hurdles to producing these documents, the more difficult it will be for plaintiffs to meaningfully digest and use them at depositions and in expert reports. Plaintiffs respectfully request that this Court deny Defendants' Motion so Plaintiffs can expeditiously begin the process of receiving, reviewing, and using these documents before it is too late.

Respectfully submitted,

/s/ Marlene J. Goldenberg

Marlene J. Goldenberg

cc: All counsel of record via ECF